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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,976	01/16/2002	Derek J. Hei	282172000902	3174
38859	7590	01/23/2006	EXAMINER	
CERUS CORPORATION C/O MORRISON & FOERSTER LLP 755 PAGEMILL ROAD PALO ALTO, CA 94304			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/051,976

Applicant(s)

HEI ET AL.

Examiner

David M. Naff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/25/05 & 10/28/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-9 and 27-59 is/are pending in the application.
- 4a) Of the above claim(s) 10-24 and 27-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-9 and 55-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/7/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

An amendment of 10/25/05 amended the specification, amended claims 2-5, 55, 56 and 59, and canceled claim 1 (25 and 26 previously canceled).

5 A supplemental amendment of 10/28/05 presented arguments and did not amend the claims.

Claims in the application are 2-9 and 27-59.

10 Claims 10-24 and 27-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/27/03.

Claims examined on the merits are 2-9 and 55-59.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15 The office actions listed on form 1449 of 11/7/05 have been considered, but have been lined through since they do not constitute prior art available to the public.

***Claim Rejections - 35 USC § 103***

20 Claims 2-9 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al (6,319,662) (listed on form PTO-1449 of 6/13/02) in view of Tsyurupa et al (193 on form 1449) and Davankov et al (110 on form 1449) and Tlustazkova et al (4,634,604), and if necessary in further view of Yamamoto et al (4,725,355) for reasons in the previous office action of 4/25/05 and for reasons herein.

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The claims are drawn to removing a free low molecular weight psoralen compound from a blood product by contacting the blood product with a hypercrosslinked resin to remove at least substantially all of the free psoralen compound. The resin is not pre-wetted prior to  
5 contacting with the blood product. Claims 55-59 additionally require brominated psoralen, the resin to be nonionic and the free psoralen to comprise free psoralen and free low molecular weight psoralen photoproduct.

Foley et al disclose adding a psoralen compound such as 4'-  
10 aminomethyl-4,5',8-trimethyl psoralen (AMT) (col 5, lines 29-32) to blood to inactivate viral contaminants, and then removing the AMT from blood with a material having affinity for the AMT such as activated charcoal, an ion exchange agent or biobeads (col 5, lines 10-13 and line 31).

15 Tsyurupa et al and Davankov et al disclose using hypercrosslinked polystyrene polymer or hypercrosslinked styrene-divinylbenzene copolymers as a sorbent for removal of a variety of organic compounds from aqueous mediums. The hypercrosslinked copolymers have exceptional high adsorption capacity. See Tsyurupa et al (page 69,  
20 right col, lines 14-17, and page 70, left col, lines 6-10, and right col, paragraph (3). Also, see Davankov et al (page 27, page 37, right col, first full paragraph, paragraph bridging pages 37 and 38 and paragraph bridging pages 40 and 41). Tsyurupa et al disclose that the adsorption capacity of macroporous Amberlite XAD-2 is significantly  
25 smaller than that of hypercrosslinked polystyrenes (page 73, sentence

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bridging the columns). Further disclosed by Tsyurupa et al is using the hypercrosslinked copolymer removing organic substances from biological liquids and blood (page 75, right col, number 8).

5 Tlustazkova et al disclose using styrene-divinylbenzene copolymers such as XAD-2 and XAD-4 as an sorbent to remove toxic compounds from blood (col 1, lines 9-15 and 26-32, and col 2, lines 19-22).

10 Yamamoto et al disclose that it is known to use a styrene-divinylbenzene copolymer as a blood purification sorbent (col 2, lines 7-10).

It would have been obvious to us as the material having affinity for AMT of Foley et al, the hypercrosslinked polystyrene-divinylbenzene copolymer taught by Tsyurupa et al and Davankov et al for the expected advantage of the hypercrosslinked copolymer providing  
15 exceptional adsorption capacity since it would have been expected from Tlustazkova et al, and if needed Yamamoto et al, that a polystyrene-divinylbenzene copolymer can be used for removing toxic compounds from blood. Tsyurupa et al disclose using the hypercrosslinked copolymer to adsorb and remove numerous different organic compounds including  
20 organic substances from biological fluids such as blood (page 75, right col, section 8) and synthetic dyes (page 76, right col, section 9), and it would have been expected the hypercrosslinked copolymer can be an effective adsorbent for removing a psoralen compound from blood. The hypercrosslinked copolymer of Tsyurupa et al and Davankov et al is  
25 nonionic as in claims 56-58. Not pre-wetting as in claim 4 would have

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been obvious since Tsyurupa et al and Davankov et al do not disclose that pre-wetting is essential when using the hypercrosslinked polystyrene-divinylbenzene copolymers as an absorbent. Even if the references disclosed that pre-wetting is required, it would have been obvious to omit pre-wetting if its function is not desired. Free psoralen compounds in blood will inherently be a mixture as required by claim 59.

### ***Response to Arguments***

Applicants urge that the references fail to disclose not pre-wetting as in claim 4. However, as noted above, Tsyurupa et al and Davankov et al do not disclose that pre-wetting is required. If the references do not teach that pre-wetting is essential, there is no reason to use pre-wetting. Additionally, Foley et al does not disclose that pre-wetting is essential.

### ***Claim Rejections - 35 USC § 103***

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-9 and 56-59 above, and further in view of Park et al (5,789,601) for reasons in the previous office action of 4/25/05 and for reasons herein.

The claim requires the psoralen to be brominated psoralen.

Park et al disclose using brominated psoralen (col 20, line 30) for inactivation of viral and bacterial contaminants in blood.

When using a hypercrosslinked copolymer as the material of Foley et al having affinity for a psoralen compound, it would have been

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obvious to use brominated psoralen as the psoralen compound as suggested by Park et al.

***Response to Arguments***

In traversing this rejection, applicants rely on reasons  
5 presented in regard to claims 2-9 and 56-59. As set forth above, these reasons are unpersuasive.

***Double Patenting***

Claims 2-9 and 55-59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable  
10 over claims 1-47 of U.S. Patent No. 6,544,727 B1 or claims 1-45 of U.S. Patent No. 6,951,713 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention would have been obvious from the claims of the patents drawn to using an adsorbent material, which can  
15 be a hypercrosslinked resin that does not require pre-wetting for use to remove psoralen compounds from blood products.

***Response to Arguments***

Applicants urge that double patenting over 6,544,727 B1 is improper since a device and method were restricted in 08/660,910.  
20 However, 6,544,727 is not a division of 08/660,910, and the system claimed in this patent is not a result of restricting in 08/660,910.

***Double Patenting***

Claims 2-9 and 55-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as  
25 being unpatentable over claims 53, 57-59, 107, 108 and 111-114 of

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compending Application No. 09/972,323, claims 1-68 of compending Application No. 11/243,822, or claims 1-3 and 5-25 of compending Application No. 09/872,384. Although the conflicting claims are not identical, they are not patentably distinct from each other because  
5 the presently claimed invention would have been obvious from the claims of the compending applications drawn to using an adsorbent material which can be a hypercrosslinked resin that does not require pre-wetting to remove psoralen compounds from blood products.

This is a provisional obviousness-type double patenting rejection  
10 because the conflicting claims have not in fact been patented.

#### ***Response to Arguments***

Applicants state that double patenting rejections will be addressed when claims are otherwise allowable.

#### ***Conclusion***

15 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date  
20 of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,




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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
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